

REMARKS

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

New claims 38-47 have been added. Support for these new claims is found in the specification at page 13, lines 9-10. In addition, new claims 42-44 are supported by original claim 11, and new claims 45-47 are supported by claim 15. No new matter has been added by these new claims.

The rejection of claims 1-17 and 37 under 35 U.S.C. § 112 (1st para.) for containing new matter that is not supported by the written description is respectfully traversed in view of the above amendments to claim 1.

The rejection of claims 1-10, 12-14, 16, 17, and 37 under 35 U.S.C. § 112 (1st para.) for lack of an adequate written description is respectfully traversed in view of the amendments to claim 1 and the following remarks. The U.S. Patent and Trademark Office (“USPTO”) has taken the position that the instant application fails to describe in sufficient detail methods for conferring tolerance to salt and drought stress in plants by transforming the plants with expression cassettes containing components *other* than the specific components contained in plasmids pJS112, pJP21, and pJPM001 taught in the instant application. The USPTO has set forth various grounds to support this rejection. As described in more detail below, applicants assert that the grounds for rejection lack merit.

The USPTO has the initial burden of presenting, by a preponderance of evidence, why a person skilled in the art would not recognize that applicants were in possession of the claimed invention at the time of filing. *See* Manual of Patent Examining Procedure (“MPEP”) § 2163.04, at 2100-179 (Rev. 2, May 2004); *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). Applicants respectfully submit that the USPTO has failed to satisfy this burden for all three grounds. Nevertheless, applicants provide the following reasons as to why the USPTO’s grounds for rejection lack merit.

With respect to the first ground, the USPTO has asserted that the specification does not describe “transforming the plants with expression cassettes comprising other abscisic acid response complex units of different structure obtained from other sources, or other minimal promoters of different structure obtained from other sources that have been truncated, or other Hva22 introns” (Office Action, page 5, lines 10-12). Applicants disagree. The specification describes abscisic acid response complex (“ABRC”) units from the barely *HVA22* gene and the barley *HVA1* gene. Given the skill and knowledge in the art with respect to ABRC units, the skilled artisan would readily understand the common attributes associated with ABRC units. Thus, applicants submit that the two disclosed ABRC units are

sufficient representatives of a genus of ABRC units. *See* MPEP § 2163 at 2100-175. Regarding the “minimal promoter” element, applicants point out that claim 1 has been amended to further limit the “minimal promoter” element to those recited in claim 5 (now canceled). In particular, claim 1 now recites that the “minimal promoter is Act1-100 of rice, a truncated α -amylase promoter of barley or rice which retains its function, a truncated maize ubiquitin promoter which retains its function, or a truncated CaMV 35S promoter which retains its function.” These minimal promoters were identified in the specification at page 12, lines 3-6. Further, because the truncated promoters must retain their function (as recited in the claims), and because the recited truncated promoters are well known in the art, the skilled artisan art would reasonably conclude that applicants were in possession of the claimed invention.

For example, one of ordinary skill in the art would understand that, in order to function as a promoter, the truncated version must include such essential elements as a TATA box (or the like). Further, the teaching in the art identifies specific “minimal” or “truncated” promoters such as those claimed. In particular, the Act1-100 minimal promoter is described and shown to be active in Examples 15-31 of the specification, which corresponds to Su et al., “Dehydration-Stress-Regulated Transgene Expression in Stably Transformed Rice Plants,” *Plant Physiol.* 117:913-922 (1998) (“Su”) (attached hereto as **Exhibit A**). As reported in Lu et al., “Three Novel MYB Proteins with One DNA Binding Repeat Mediate Sugar and Hormone Regulation of α -Amylase Gene Expression,” *Plant Cell* 14:1963-1980 (2002) (“Lu”) (attached hereto as **Exhibit B**), a truncated α -amylase promoter of barley was described and shown to be active. Likewise, a truncated CaMV 35S promoter has been identified, and shown to be active, as discussed in Odell et al., “Identification of DNA Sequences Required for Activity of the Cauliflower Mosaic Virus 35S Promoter,” *Nature* 313:810-812 (1985) (“Odell”) (attached hereto as **Exhibit C**). In view of the description of minimal promoters in the specification, as well as the level of knowledge in the art of the recited truncated promoters, applicants respectfully submit that one of skill in the art would reasonably conclude that applicants were in possession of the recited truncated promoters at the time of filing.

Regarding the second ground for rejection, the USPTO has argued that the specification does not describe “expression cassettes comprising the recited components operably linked in other configurations, or operably linked to permit expression of the DNA molecule in leaves or root of the plant” (Office Action, page 5, lines 13-16). Applicants submit that this ground for rejection has been obviated by amending claim 1 to delete the phrase “in leaves or roots of the plant.”

As to the third ground for rejection, the USPTO has taken the position that the specification does not disclose a representative number of species of expression cassettes to support the “claimed genus of expression cassettes whose components are operably linked to *both* permit expression of a DNA molecule in leaves or root of the plant *and* confer tolerance to salt stress and drought stress in the plant upon expression of said DNA molecule, nor the structural features unique to the genus” (Office Action, page 6, lines 1-5). As with the second ground of rejection, applicants submit that this ground has been obviated by the amendments to claim 1.

The rejection of claims 1-10, 12-14, 16, 17, and 37 under 35 U.S.C. § 112 (1st para.) for lack of enablement is respectfully traversed. The USPTO has taken the position that the specification, while enabling for methods of conferring tolerance to salt stress and drought stress in plants transformed with the expression cassettes contained in plasmids pJS112, pJP21, and pJPM001, does not provide enablement for other methods requiring transformation with other expression cassettes. Applicants respectfully disagree. The basic techniques used to construct expression cassettes are well known in the art. The specification (*see, e.g.*, pages 10-12 and Examples 15-30) provides adequate disclosure to enable one of ordinary skill in the art to prepare the expression cassette recited in claim 1. In particular, the specification identifies the three key components that must be included in the expression cassette of the present invention. The plasmids identified by the USPTO (*i.e.*, pJS112, pJP21, and pJPM001) are working examples of how to make the expression cassette with an Act1-100 promoter. Based on this teaching, one of ordinary skill in the art would be able to make, without undue experimentation, expression cassettes with the other recited minimal promoters. This is supported by Lee et al., “Expression of *Arabidopsis* CBF1 Regulated by an ABA/Stress Inducible Promoter in Transgenic Tomato Confers Stress Tolerance Without Affecting Yield,” Plant Cell Environ 26:1181-1190 (2003) (“Lee”) (attached hereto as **Exhibit D**).

In Lee, tomato plants were transformed with the CRT/DRE binding factor 1 (“*CBF1*”) gene of *Arabidopsis thaliana*. The *CGF1* gene was previously shown to improve tolerance to cold, drought, and salt loading in tomatoes using a strong constitutive CaMV 35S promoter (*Id.* at 1181-1182). However, the transgenic plants were shown to have decreased yield under normal growth conditions (*Id.* at 1181). Lee reports transformation of tomato using an expression cassette including an ABRC unit from the barley *HAV22* gene linked to a truncated α -amylase promoter of barley (*i.e.*, amy64) to drive expression of the *Arabidopsis* *CGF1* gene. The results show that the resulting transgenic tomatoes exhibit enhanced tolerance to chilling, water-deficit, and salt stress, *without* sacrificing yield. Lee (at 1182)

describes using the techniques of Su for constructing the expression cassette. As indicated above, Su was co-authored by the co-inventors of the present invention and is included in the specification as Examples 15-31.

In view of the foregoing remarks and the amendments to claim 1, applicants respectfully submit that the rejection for lack of enablement is improper and should be withdrawn.

The rejection of claims 1-17 and 37 under 35 U.S.C. § 112 (2nd para.) for indefiniteness is respectfully traversed in view of the above amendments to claim 1, the cancellation of claim 5, and the following remarks. The USPTO has taken the position that the term “truncated” as used in claim 5 is indefinite because the nature and extent of the truncations are unclear (*see* Office Action, at page 11). Applicants respectfully disagree. It is clear from the specification (at page 38, lines 31-32) that the term “truncated promoter” is used interchangeable with “minimal promoter.” It is well known in the art that “truncated” means shortened, and that a truncated promoter is a promoter (known in the art) that has been shortened. The specification (at page 12, lines 2-6) and original claim 5 identify particular minimal promoters as “Act1-100 of rice, a shortened α -amylase promoter of barley or rice, a shortened maize ubiquitin promoter, or a shortened CaMV 35S promoter.” Further, claim 1 recites that the truncated promoters must retain their function. One skilled in the art would readily understand the characteristic of a functional promoter versus one that was not functional. Furthermore, as already described above, a representative number of functional, truncated promoters (as recited in claim 1) are described in the art (*see, e.g.,* Su, Lu, Odell, and Lee, described above). In addition, one skilled in the art would be capable of preparing and testing promoters truncated as taught in the instant application, without undue experimentation. Further, the recitation of the plasmids of claim 11 (i.e., pJS112, pJP21, and pJPM001), as well as the description of these plasmids in the specification, gives clear guidance to allow the skilled artisan to understand the meaning of the term “truncated” as used in amended claim 1. Thus, in view of the foregoing, applicants respectfully submit that this rejection is improper and should be withdrawn.

The rejection of claims 1-4, 7, and 9 under 35 U.S.C. § 102(b) as being anticipated by Wu et al., “Production of Transgenic Rice Plants That Are Resistant to Insect Pests and Fungal Diseases or to Water and Salt Stress,” *General Meeting of the International Program on Rice Biotechnology*, Abstract 113 (Sept. 15-17, 1997) (the “Wu Abstract”) is respectfully traversed.

The Wu Abstract discloses using constitutive or ABA-inducible promoters to drive water stress or salt stress tolerance genes in rice plants. As amended, claim 1 recites


that the expression cassette must contain three elements: (i) at least one abscisic acid response complex unit; (ii) a minimal promoter (as defined in amended claim 1); and (iii) a DNA molecule that increases tolerance to salt stress and drought stress in plants. As noted above, claim 1 has been amended to further limit "minimal promoter." Because the Wu Abstract neither discloses nor suggests an expression cassette with such a "minimal promoter," this rejection is improper and should be withdrawn.

The rejection of claims 1-4, 7-10, 12-14, 16, and 17 under 35 U.S.C. § 103(a) for obviousness over the Wu Abstract in view of applicants' alleged admitted prior art is respectfully traversed in view of the above amendment to claim 1 and the above remarks with respect to the 35 U.S.C. § 102(b) rejection based on the Wu Abstract.

In view of all of the foregoing, applicants submit that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

Date: November 19, 2004



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